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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/423,863 | 02/08/2000 | FREDERIC DONIE | BMID9974US | 7240 |

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| EXAMINER | |
|---|---|
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| ART UNIT | PAPER NUMBER |
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| 1648 | 21 |

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. 09/423,863 | Applicant(s) DONIE ET AL. | |
|---|---|---|---|
| | Examiner Bao Qun Li | Art Unit 1648 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 June 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *they fail to overcome all outstanding rejections*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *None*.

Claim(s) objected to: *None*.

Claim(s) rejected: *16,17,19,23,25,29 and 30*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10.☒ Other: *See attachment*

Bao Qun Li

## *Advisory Action*

The amendment filed 06/24/2002 under 37 CFR 1.116 in reply to the final rejection has been entered, but is not deemed to place the application in condition for allowance. For purposes of appeal, the status of the claims is as follows:

**Allowed claim(s): NONE**

**Rejected claim(s): 16-17, 19, 23, 25, and 29-30.**

**Claim(s) objected to: NONE**

## *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 16, 19 and 30 are still rejected under ***35 USC § 112,*** second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 19 and 30 are vague and indefinite in that the metes and bonds of " a variant thereof" are not defined. Applicants asserted that the " variants" are the term that is well established in the art. Examples of such variant are illustrated in the Tables 8-9 of specification. A genetic variant in an anima acid sequence is simply a sequence substantially similar to the consensuses sequence but having one ore more substitutions of different amino acids into the sequence. Therefore, Applicants respectfully submit that the rejection be withdrawn.

Applicants' argument has been fully considered. However, it is not found persuasive because if the variant was derived from every one or more than one amino acids substitutions with any or all amino acids in the subtype D, they would render anonymous sequence variants, it is unclear which variants is intended. Although the claims are interpreted in light of the specification; however, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In order to overcome the rejection, Applicants are suggested to amend the claims to the precise amino acid sequences with a defined SEQ ID NO and the suitable amino acid(s) subjective to be substituted at the precise position as it is disclosed in the specification Table 8-9.

Regarding to claim 25, Applicants amend the claim referring two regions of HIV-1 subtype O. The amendment has been respectfully considered. However, it is not found persuasive because the claim still fails to define what is the precise sequence structure of epitope I and II of HIV-1 subtype O are intended. In order to overcome the rejection, Applicants are suggested to amend the claim to the precise amino acid sequences with a defined SEQ ID NO.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-17, 19, 23, 25 and 29-30 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the anti-gp41 antibody of HIV-1 group M by using mixing two sequences selected from SEQ NO: 29-39 (SEQ ID NO: 1-11) as a antigen peptide, does not reasonably provide enablement for using any or all variants of sequences encoding the epitope I and II in any kind of mixture or length for detecting the antibody against gp41of any subtype of HIV group M. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the standard for enablment is not whether the claims are limited to only expressly disclosed or preferred embodiments. Rather the standard is whether the disclosure is sufficient to engaged in undue experimentation. In the present case, the peptide sequence is relative short and readily prepared, and the general immunoassay methodologies are well known in the art and easily carried out. Accordingly, the rejection should be withdrawn.

Applicants' argument has been fully considered. However, it is not found persuasive for the reason that the specification still fails to provide a sufficient teaching and description of each

claimed sequence, especially each variant of the gp41 epitope I and II region of all HIV subtypes of group M. Those sequences are particularly important to enable the scope of the claimed invention. Because the claimed invention is directed to an improved methodology for the detecting the antibodies against all HIV-1 subtypes (claim 16 citation of an immunoassay method for detecting of an antibody against HIV does not limited to any particular group of HIV-1 virus), one skilled in the art would not be able to practice the claimed method without a full disclosure and description of all necessary sequences that are intended in the assay to ensure that specifically the subtypes of the highly diverse group M can be detected sensitively and accurately (see specification second paragraph on page 3).

In order to overcome the enablement rejection, Applicants are suggested to amend the claims to the precise amino acid sequences with a defined SEQ ID NO and the suitable amino acid(s) subject to substitution at the precise position as it is disclosed in the specification, Table 8-9.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-17, 19, 21, 23, 25, 29-30 and 32 are still rejected under 35 U.S.C. 103(a) as being unpatentable over De Ley et al. (WO 93/18054) and Chamaret et al. (FR2730493-A1) on the same ground as stated in the previous office action.

Applicants argue that the immunoassay method of the present invention involves combination of certain antigens. One possible combination cited in claim 16 involved a mixture of an antigen from HIV 1, M-group, subtype D, and an antigen from a " different HIV 1 subtype of the M group". Thus the second antigen according to claim 16 must be from a subtype other than subtype D. Applicants further assert that examiner has not provide any explanation as how

the combination of the references, each teaching an antigen from subtype D, leads to a mixture in which one of the antigens is not from subtype D. Accordingly, Applicant concludes that the rejection should be withdrawn.

Applicants' argument has been respectfully considered. However, it is not found persuasive because the explanation of the claim 16 reads on the use of any or all epitope I antigen sequence variants of the subtype D in combination with any or all epitope II antigen sequence variant of other subtype in the group M for the detection. However, the epitope II antigen sequence of other subtype, such as subtype F as disclosed in Table 2 (SEQ ID NO: 23, amendment page 9) is the same sequence of the variants of subtype D (Amendment page 9, SEQ ID NO: 20). In this situation, both epitope I and epitope II antigen sequences come from the subtype D of Group M, but it is also the mixture of two antigen sequences derived from two different subtypes of group M.

Furthermore, the broadly explanation of the claimed invention covered by some claim, such as claim 29, does not require second sequence. Therefore, both references obviously teach all elements of the claimed invention.

Hence, the Office maintains the conclusion that the claimed invention as a whole was *prima facie* obvious over the applied references.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

July 11, 2002

JAMES HOUSEL 7/15/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600